

B6/12

a sorbent material substantially filling the volume, the filter retaining the sorbent material in the predetermined volume while allowing passage of processing fluids through the filter during use of the cartridge, the sorbent material comprising a plurality of particles having a coating of a solvent that is sticky enough to cause the particles of the sorbent material to stick together and resist passage out of the opening in the tip.

Rule 112 55 56. (New) The sorbent cartridge of Claim 55, wherein the solvent is one of glycol, ethylene glycol, or propylene.

REMARKS

Of previously pending Claims 1-14, 33 and 34, the Examiner indicated that Claims 6-7 and 13-14 would be allowable if rewritten regarding Section 112 rejections and to incorporate features from intervening claims. Those claims are rewritten as New Claims 53-56. The Examiner rejected the remaining claims under Section 112, or as anticipated or obvious, primarily on Coplan or White, but including other references for some features of the dependent claims. In view of this Amendment and the comments herein, reconsideration and withdrawal of the rejections are respectfully requested. New Claims 35-56 are added, and are believed allowable as discussed below.

I. Section 112 Rejections

Claims 4-7 and 8-14 were rejected under 112 ¶2. The Applicants respond as follows:

Claims 4 & 11: These claims were said to omit an essential element in the form of a structural means for holding the sorbent material in the pipette tip, and thus were said to not particularly point out and distinctly claim the invention under 112 ¶2, based on MPEP 2172.01. The Examiner is requested to reconsider and withdraw the rejection in view of the following comments.

The MPEP says that to be a critical feature, the specification must identify the feature as critical. MPEP 2164.08 c. If this rejection is maintained, the Examiner is requested to identify where in the application the “means” identified by the Examiner is said to be critical.

Moreover, the MPEP says that “features which are merely preferred are not to be considered critical.” *Id.* Claims 4 & 11 define the size of the opening in the tip as being “from about 2-10 times the size of the material used in the sorbent material.” The specification says that

“Preferably, the size of the opening in the tip is from about 2-10 times the size of the material used in the sorbent material.” Pg. 2, lines 29-30. According to MPEP 2172.01, that shows that the features of Claim 4 & 11 are not critical features.

The specification explains several ways to retain the sorbent, as for example at page 9, lines 4-112, and page 10, lines 5-8, and no single one was defined as critical. The ability to pack the sorbent in to the tip sufficiently tightly to prevent unintended removal indicates that there is no missing “means” or structural feature on the pipette tip having the defined opening, as speculated by the Examiner. Given the above, Claims 4 & 11 are believed to meet the requirements of particularly pointing out and distinctly claiming the invention as required by Section 112 ¶2.

Claim 5: The Examiner rejected Claim 5, saying it was unclear what structural element(s) were added by Claim 5. The claim defines a way to pack the sorbent into the tip by drawing the sorbent and solvent through an opening in the tip and passing the solvent through a porous barrier. The patent procedure allows a claimed combination or product, made by a specific process such as that of Claim 5. In rejecting Claim 5 on the merits, the Examiner viewed Claim 5 as a product-by-process claim, which is a permissible form of claim. Thus, reconsideration and withdrawal of the rejection is respectfully requested.

Claims 6 & 13: The Examiner found the use of “sticky enough” to be indefinite, and found a lack of antecedent basis because Claim 6 (and Claim 13) also implied more than one sorbent material while parent Claim 1 (and Claim 13) was read as claiming only one sorbent material.

Tuning first to the one sorbent versus plural sorbent aspect, the specification at page 7, lines 10-12 states that “The sorbent material 24 typically comprises small, uniformly sized spherical media of silica or polymeric resin or other material onto which are bonded various chemical coatings.” Because the claim is interpreted in light of the specification, and because the nature of media is believed understood by one skilled in the art, the reference to sorbent material in Claims 1 and in Claim 6 are believed consistent, and definite to one skilled in the art. The same applies to Claim 13.

Further, the reference to “sticky enough” is believed definite, as the claims define criteria for evaluating that term when it defines: “sticky enough to cause the sorbent material to stick together and resist passage out of the opening in the tip.” The claim language is believed sufficiently definite.

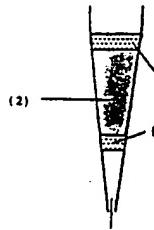
Nonetheless, Claims 6 and 13 are amended for clarity. Amended Claims 6 & 13 define particles with a coating sticky enough to cause the particles to stick together as defined in the claim. Reconsideration and withdrawal of the Section 112 rejection is respectfully requested.

Claims 7 & 14: These claims contained a typographical error and thus referred to “propolyene” when each should have referred to “propylene.” The claims are amended to define the chemical that one skilled in the art would recognize was intended by the original, albeit misspelled, term. The reference to a known material broadens the claim. Claim 14 is also amended to delete a reference to “slurry” and that removal is believed to not narrow the claim as well as ensure there is no lack of antecedent basis.

Claim 8 (& Dep. Claims 9-10): Claim 8 was said to lack antecedent basis for “the barrier” in lines 5-6. The claim has been amended to refer to “the filter” which the Examiner noted was in line 4 of the claim. Dependent Claim 10 is also amended to refer to “filter.” These amendments do not narrow the claim, but are believed to resolve the Examiner’s rejections. Thus, reconsideration and withdrawal of the Section 112 rejections are requested.

Claim 12: The Examiner found this claim unclear as to what additional structural element was added, and questioned whether the claim defined a syringe capable of containing a fluid. The claim actually, and clearly, says that “the syringe contains a fluid drawn from the distal opening through the sorbent material and filter.” That seems sufficiently clear in defining the syringe as actually containing the fluid. The specified fluid comprises a further feature of the claimed combination.

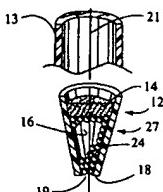
II. Section 102 Rejection of Claims 1, 8-10 & 33 On Colpan



These claims were said to be anticipated by Colpan, shown here on the left.

(2) (3a) (3b) Applicants enclose the PCT version of that patent which includes an English abstract. Coplan uses two porous barriers 3a, 3b, with sorbent media trapped between them, and with an empty space between the opening in the tip and the closest barrier 3b.

As described in the specification, and as seen from the adjacent illustration on the right, the Applicants locate the sorbent in the space between the opening in the tip and the barrier closest to the tip. That is not shown in Coplan. The claims have been



amended to clarify that the sorbent is in the spot that is empty in Coplan.

Claim 1 defines the sorbent volume as extending from the opening toward the barrier. Independent Claim 8 defines a volume that extends between the barrier and the distal opening. Independent Claim 33 specifies that no porous barrier is interposed between the opening and said means. Reconsideration and withdrawal of the Section 102 rejections based on Colpan is thus requested. Independent Claim 33 defines a sorbent material adjacent at least the opening.

Reconsideration and withdrawal of the rejection is thus respectfully requested.

A. Section 103 Rejection of Claim 5 on Colpan

Claim 5 was rejected as obvious over Colpan. Claim 5 depends from Claim 1, and is believed allowable for that reason. For example, there is nothing in Colpan to show or suggest placing sorbent between the opening in the tip, and the internal, porous barrier closest to the tip, thus Colpan cannot render Claim 5 obvious.

III. Section 103 Rejection of Claims 1-5, 8-12 and 33-34 on Colpan In View Of White

The patent to White was said to disclose the combinations defined in Claims 1-5, 8-12 and 33-34, except it “fails to disclose a porous barrier in the tapered cavity which allows processing fluids therethrough but prevents passage of the sorbent material out of the sorbent volume. Colpan was cited for that deficiency. The references cannot be properly combined, and if combined do not meet the claim requirements.

To establish even a prima facie case of obviousness, three basic criteria must be met. First, there must be some suggestion or motivation, either in prior art references or in the knowledge generally available to one of ordinary skill in the art, to modify a reference or to combine reference teachings. Second, there must be a reasonable expectation of success. Finally, the prior art reference (or references when combined) must teach or suggest all the claim limitations. The teaching or suggestion to make the claimed combination and the reasonable expectation of success must both be found in the prior art, not in Applicant’s disclosure. In re Vaeck, 947 F.2d 488 (Fed. Cir. 1991), M.P.E.P. § 2143. None of these three criteria are met.

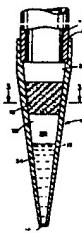
A. Even The Combined References Do Not Achieve The Claimed Combination

Neither White nor Colpan show the use of a sorbent between the opening in the tip of the

pipette or syringe, and the nearest porous barrier contained in the pipette or syringe. Neither reference alone, or in combination, achieves the combination defined in the amended claims.

B. There Is No Reasonable Expectation of Success

White, as shown here, draws and subsequently ejects a predetermined volume of liquid into and out of a syringe. In order to prevent any liquid or vapor from entering and contaminating the remainder of the syringe, White places a plug 18 of hydrophilic particles that expand upon contact with liquid to block flow through the plug. That hydrophilic plug prevents liquid and vapors from passing through the plug, but allows gasses to pass so that liquid can be drawn into the tip of the pipette and later expelled from the pipette tip. The plug is expressly designed to block fluid flow through the plug, and the plug will expand and block flow if it even contacts the liquid or liquid vapor. Col. 2, lines 32-36 (“if the liquid sample itself by some chance comes into contact with the plug member, sufficient hydrophilic particles will expand to completely block the plug member and make the pipette inoperative”).



White also lacks any sorbent between the barrier and the opening in the pipette tip.

It is unclear, but it appears that the Examiner proposes using White’s hydrophilic plug in place of barrier 3a in Colpan (the barrier most distant from the tip), so that there is a sorbent material between the barrier and the opening in the pipette tip as required by the claims. If the hydrophilic barrier is used as the barrier closest to the opening in the tip, then no fluid whatsoever can be passed from the opening through the sorbent, or from the main body of the syringe through opening. That seems to negate, if not radically alter, the use of the syringe - without any teaching in the art to do so.

If White’s barrier is used as barrier 3a in Colpan, then that combination also fails for several reasons. First, White teaches a pipette tip for transferring liquid with extreme measures taken to avoid contaminating the liquid. White teaches the need to avoid having the liquid even contact any barrier. Col. 1, lines 65-67 (“even contact with the barrier itself may give rise to contamination of the drawn sample by the barrier material”). The proposed modification forces liquid into contact with barrier which is contrary to the teachings of White, so there is no reasonable expectation of success.

Further, White teaches that contact of the liquid with the barrier also destroys the accuracy

with which precise amounts of liquid are measured. Col. 1, lines 65-68 (“even contact with the barrier itself ... also gives rise to inaccuracies in the amount of liquid dispensed”). The Examiner’s proposed modification would place sorbent between the hydrophilic barrier of White and the opening in the tip. That proposed modification forces liquid into contact with the barrier and destroys the accuracy of the measured sample, contrary to White’s teaching.

White in fact teaches the need for an air gap between the barrier and the liquid, of 10-40% of the volume in the tip. Col. 2, lines 39-44. The Examiner’s proposed modification destroys this, and instead places contaminating media in that volume.

White also teaches that contact with any barrier, such as that proposed by the Examiner, will cause a wicking effect drawing liquid into the syringe where contamination can occur. Col. 1, lines 56-60 (“if liquid actually contact such a barrier, it will be drawn along the barrier by a wicking effect to the upper side, where there is nothing preventing it from contacting the suction device”).

Moreover, inserting a barrier in Colpan destroys Colpan. That construction is intended to have liquid pass through both porous barriers. The abstract in the PCT counterpart of that patent shows this. To block flow through one barrier renders the device useless.

It is improper to combine references where to modify the primary reference would “destroy its structural identity and mode of operation.” *Ex parte Jackson*, 146 USPQ 409, 410 (PTO Bd. App. 1964); *See Ex. parte Hartman*, 186 USPQ 336, 367 (PTO Bd. App. 1974) (improper to combine references “since to do so would destroy that on which the invention is based”). The Examiner’s proposed modification is contrary to White’s teachings, and destroys its mode of operation, and is contrary to the way Colpan works, and destroys the utility of Colpan. That negates any reasonable expectation of success of the proffered combination.

C. There Is No Motivation To Ignore White’s Teachings & Combine The References

Moreover, the proposed reason for the modification is without support in the record. It appears to be fabricated based on the desire to combine features from two inconsistent patents so as to achieve the structure defined in the claims. But the Examiner must not only explain the motivation for modifying or combining references, the Examiner must also point to some concrete evidence in the record supporting the motivation to modify or combine.

As an administrative tribunal, the Board clearly has expertise in the subject matter over which it exercises jurisdiction. This expertise may provide sufficient support for conclusions as to peripheral issues. With respect to core factual findings in a determination of patentability, however, **the Board cannot simply reach conclusions based on its own understanding or experience - or on its assessment of what would be basic knowledge or common sense.** Rather, **the Board must point to some concrete evidence in the record in support of these findings.** To hold otherwise would render the process of appellate review for substantial evidence on the record a meaningless exercise. [*In re Zurko*, 59 USPQ2d 1693, 1697 (Fed. Cir. 20010) (emphasis added)].

As discussed above, White teaches against the proposed combination. Here, there is no basis in the record of why one skilled in the art would go against the teachings of White and make the proposed combination. Indeed, there is no showing that the proposed combination is even desirable or has any practical application. To the contrary, the above discussion shows why the proposed combination has no reasonable basis for success. Colpan states that “the solution is forced through the device” (Abstract) but the porous barrier of White would prevent that. The hydrophilic barrier in the speculative apparatus fabricated by the Examiner to reject the claims just won’t work for the intended purpose of Colpan.

The Examiner is urged to avoid the insidious temptation of using hindsight to select features from two isolated references and fabricate a reason to combine those references. If the rejection is maintained, the Examiner is requested to meet the required burden of point to some concrete evidence in the record in support of the proposed combination and the reasons for that modification of the references, as required by the court in *Zurko*.

D. Conclusion On Obviousness

The above comments apply primarily to the independent claims. If the independent claims are allowable, the dependent claims also believed to be allowable. In particular, even if the references are combined, the combination defined in the amended claims are not believed to be met, and thus even the combinations defined in the dependent claims are not met. The Applicants

disagree with the rationale given in rejecting the dependent claims, but do not elaborate on the deficiencies of those rejections in view of the comments on the independent claims. The Examiner is requested to reconsider, and withdraw the rejections on all claims.

IV. New Claims:

Claims 6-7 and 13-14 were deemed allowable if rewritten to overcome Section 112 rejections and to include the features of the intervening claims. Office Action at 17. They are revised as discussed above regarding the Section 112 rejections. They are resubmitted as New Claims 53-56. Claim 53 corresponds to original Claim 6, and Claim 55 corresponds to original Claim 13.

Claims 35-52 are submitted to broaden the scope of the claims. They are believed allowable and such allowance is requested.

V. Conclusion

For the above reasons, the claims are believed to be in a condition for allowance and such allowance is respectfully requested. If the Examiner has any questions, please contact the undersigned in order to resolve any matters over the phone and to pass the application to issuance.

Respectfully submitted,

Date: 6/17/02

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Claims Marked To Show Changes In Claims

1. (Once Amended) A sorbent cartridge for use in preparing samples for chemical analysis, comprising:

a pipette tip having a longitudinal axis and a hollow distal tip with tapered walls defining an interior cavity extending along the axis and opening at a distal end of the tip;

a porous barrier in the tapered cavity placed at a predetermined location in the tip to define a sorbent volume between the barrier, the cavity walls and the opening at the distal end of the tip, the barrier allowing processing fluids to pass through the barrier; and

a sorbent material in the sorbent volume and extending from the opening toward the barrier, the sorbent material being selected for use in the chemical analysis and the barrier being selected to prevent passage of the sorbent material out of the sorbent volume.

6. (Once Amended) The sorbent cartridge of Claim 1, wherein the sorbent material comprises a plurality of particles with [has] a coating of a solvent on the particles that is sticky enough to cause the particles [sorbent material] to stick together and resist passage out of the opening in the tip.

7. (Once Amended) The sorbent cartridge of Claim 5, wherein the solvent is one of glycol, ethylene glycol or propylene [propylene].

8. (Once Amended) A sorbent cartridge, comprising:

a pipette tip having an interior cavity in fluid communication with a distal opening located in the tip;

a filter placed in the tip and defining a predetermined volume that extends between the barrier and the distal opening; and

a sorbent material substantially filling the volume, the filter [barrier] retaining the sorbent material in the predetermined volume while allowing passage of processing fluids through the filter during use of the cartridge.

10. Once Amended) The sorbent cartridge of Claim 8, wherein the predetermined volume is tapered toward the distal opening to form a frusto-conical shaped cavity and the [porous barrier] filter comprises a frusto-conical filter.

11. (Once Amended) The sorbent cartridge of Claim 8, wherein the sorbent material comprises particles having diameters and wherein the distal opening has a diameter of about 2-10 times the maximum diameter of the sorbent material.
13. (Once Amended) The sorbent cartridge of Claim 8, wherein the sorbent material comprises a plurality of particles having [has] a coating of a solvent that is sticky enough to cause the particles of the sorbent material to stick together and resist passage out of the opening in the tip.
14. (Once Amended) The sorbent cartridge of Claim 13, wherein the [slurry] solvent is one of glycol, ethylene glycol, or propylene [propylene].
33. (Once Amended) A sorbent cartridge for use in preparing samples for chemical analysis, comprising:

a hollow tip having an opening in a distal end;
means in the tip for retaining a porous barrier at a predetermined location to define a sorbent volume between the barrier and the opening the hollow tip, with no porous barrier being interposed between the opening and said means; and
a sorbent material between the opening and said means retained in the sorbent volume by the porous barrier for use in the chemical analysis, the barrier allowing passage of fluids but not the sorbent material, during use of the sorbent cartridge.

35. (New) A sorbent cartridge for use in preparing samples for chemical analysis, comprising:

a tip having a longitudinal axis and a distal tip having cavity walls that define an interior cavity extending along the axis with an opening at a distal end of the tip;
a porous barrier in the cavity placed at a predetermined location in the tip to define a sorbent volume between the barrier, the cavity walls and the opening at the distal end of the tip, the barrier allowing processing fluids to pass through the barrier; and
a sorbent material in the sorbent volume and extending from the opening toward the barrier, the sorbent material being selected for use in the chemical analysis and the barrier

being selected to prevent passage of the sorbent material out of the sorbent volume.

36. (New) The sorbent cartridge of Claim 35, wherein the cavity walls at the opening extend toward the longitudinal axis to form a lip that helps retain the sorbent in the cavity.

37. (New) The sorbent cartridge of Claim 35, wherein the tip forms a tapered cavity ending at the distal end.

38. (New) The sorbent cartridge of Claim 35, wherein the sorbent material substantially fills the sorbent volume.

39. (New) The sorbent cartridge of Claim 35, wherein the sorbent comprises a plurality of particles coated with a material that helps prevent the sorbent from sliding out the opening.

40. (New) The sorbent cartridge of Claim 39, wherein the particles are coated with propylene glycol.

41. (New) The sorbent cartridge of Claim 39, wherein the particles are coated with ethylene glycol.

42. (New) The sorbent cartridge of Claim 39, wherein the particles are coated with glycerol.

43. (New) The sorbent cartridge of Claim 35, wherein the sorbent comprises a plurality of particles filling between about 50-60% of the sorbent volume.

44. (New) The sorbent cartridge of Claim 35, further comprising one of a frit or screen at the opening and placed to prevent sorbent from passing out of the opening.

45. (New) The sorbent cartridge of Claim 35, wherein the sorbent material comprises particles having diameters and wherein the distal opening has a diameter of about 2-10 times the maximum diameter of the particles.

46. (New) A sorbent cartridge for use in preparing samples for chemical analysis, comprising:

a tip having a longitudinal axis and a distal tip having cavity walls that define an interior cavity extending along the axis with an opening at a distal end of the tip;

a porous barrier at not more than one location inside the cavity in the tip and defining a sorbent volume between the porous barrier, the cavity walls and the opening at the distal end of the tip, the porous barrier allowing processing fluids to pass through the barrier; and

a sorbent material in the sorbent volume and extending from the opening toward the barrier, the sorbent material being selected for use in the chemical analysis and the barrier being selected to prevent passage of the sorbent material out of the sorbent volume while allowing the passage of liquids.

47. (New) The sorbent cartridge of Claim 46, wherein the tip is tapered toward the opening in the distal end of the dip.

48. (New) The sorbent cartridge of Claim 47, wherein the sorbent material substantially fills all of the sorbent volume.

50. (New) The sorbent cartridge of Claim 46, wherein the distal tip is conical.

51. (New) The sorbent cartridge of Claim 46, wherein the distal tip is tapered at least immediately adjacent the opening in tip.

52. (New) A sorbent cartridge for use in preparing samples for chemical analysis, comprising:

a tip having a longitudinal axis and a distal tip having cavity walls that define a tapered interior cavity extending along the axis with an opening at a distal end of the tip;

a porous barrier at not more than one location inside the cavity in the tip and defining a sorbent volume between the porous barrier, the cavity walls and the opening at the distal end of the tip, the porous barrier allowing processing fluids to pass through the barrier; and

a sorbent material in the sorbent volume and extending from the opening to the barrier, the sorbent material being selected for use in the chemical analysis and the barrier being selected to prevent passage of the sorbent material out of the sorbent volume while allowing the passage of liquids.

53. (New) A sorbent cartridge for use in preparing samples for chemical analysis, comprising:

a pipette tip having a longitudinal axis and a hollow distal tip with tapered walls defining an interior cavity extending along the axis and opening at a distal end of the tip;

a porous barrier in the tapered cavity placed at a predetermined location in the tip to define a sorbent volume between the barrier, the cavity walls and the opening at the distal end of the tip, the barrier allowing processing fluids to pass through the barrier; and

a sorbent material in the sorbent volume, the sorbent material being selected for use

in the chemical analysis and the barrier being selected to prevent passage of the sorbent material out of the sorbent volume, the sorbent material comprising a plurality of particles with a coating of a solvent on the particles that is sticky enough to cause the particles to stick together and resist passage out of the opening in the tip.

54. (New) The sorbent cartridge of Claim 53, wherein the solvent is one of glycol, ethylene glycol or propylene.

55. (New) A sorbent cartridge, comprising:
a pipette tip having an interior cavity in fluid communication with a distal opening located in the tip;
a filter placed in the tip and defining a predetermined volume between the barrier and the distal opening; and

a sorbent material substantially filling the volume, the filter retaining the sorbent material in the predetermined volume while allowing passage of processing fluids through the filter during use of the cartridge, the sorbent material comprising a plurality of particles having a coating of a solvent that is sticky enough to cause the particles of the sorbent material to stick together and resist passage out of the opening in the tip.

56. (New) The sorbent cartridge of Claim 55, wherein the solvent is one of glycol, ethylene glycol, or propylene.